or other shaped reconstitution form wherein the value of our invention is clearly unique and evident.

2. **Claims 25, 26, 29-31 and 33-35 are rejected under 35 U.S.C. 102 (b) as being anticipated by Luck et. Al. (US 4,233,360).**
Luck provides a general method for extraction and purification of collagen which will not lproduce a good quality fibrillar collagen from the tuna fish sources provided and therefore do not predict or teach a specific applicable method for pure medical grade Type I Collagen from a tuna tendon source. Methods by Luck may apply to mammalian collagens in a broad sense but lack the specificity needed to address temperature instability and pH sensitivity of tuna tendon thereby potentially resulting in a very pure high fibrillar collagen suitable for further reconstitution and product application.
    - Our invention utilizes specific processing to preserve strong long fibrillar fibers from tuna tendon. Enzymes are used to address telopeptides with the deactivation method being oxidation for complete inactivation with bleaching as opposed to caustics.
    - Tuna tendon collagen is very sensitive to pH and extremely easy to denature at elevated pH and temperature. This is true, in varying form, of all cold blooded animals. Mammalian tissues in process are generally much less sensitive to the previously mentioned conditions and their manipulation. This is due to the difference in collagen 'melt temperature' differences between warm and cold blooded animals.
    - Luck does not teach or predict the specific process we practice in production of our tuna tendon sourced collagen. We do not need salt or dialysis to produce the collagen that is the subject of our process,...and our purity is greater that Luck's due to a additional precipitate 'polishing' step addressing un-reacted collagen materials.
    - Purity and chain structure of our collagen has bearing on the method employed in our invention since specific structure impact the fibrillar collagen obtained and are directly linked to products thereof. As it happens, our process also satisfactorily addresses many other species with similar results. That said however, a unique observation was the appearance of a fibrillar form of purified tuna tendon Type I Collagen exhibiting unexpected length, strength and capable of further processing into various medical devices usually reserved for mammalian sourced materials.

3. **Claims 21-35 are rejected under 35 USC 103(a) as being unpatentable over Luck et. al. in view of Shadwick et. al.**
The fact is that neither Luck nor Shadwick provide the information required to anticipate the appearance of tuna tendon sourced Type I Collagen by their processing procedures.
    - Shadwick analyzes and characterizes collagen components,...not the unique fibrillar structure discovered in our invention.
    - Luck speaks generally to collagen,...not to fish (tuna) tendon sourced Type I Collagen and employs salts and dialysis not suitable for fish collagens. Further,

this broad patent, when applied to cold blooded fish tissues, will result in particle collagen forms unsuitable for the desired medical device products thereof.

Conclusion:

- Shadwick identifies a fish tendon as a material containing Type I Collagen but fails to identify a unique procedure for obtaining very high collagen purity from this source that is fibrillar and can be reconstituted and perform in a manner similar to mammalian Type I Collagen. The material cannot be patented,...but the process by which a unique fibrillar structure is obtained can be the subject of a patent as having uniqueness and utility. Therefore Shadwick merely stated the obvious that Type I Collagen is present in tuna tendon,...he did not provide any grounds for processing the material to produce strong temperature stable fibrillar forms.
- Process results in very high Type I Collagen very comparable to mammalian Type I Collagen,...in fact many other species previously unsuitable for purification due to temperature instability also respond excellently to our process invention. Fish, as cold blooded animals, have decreased collagen temperature stability. Tuna tendons exhibit higher temperature stability however, previous attempts to obtain stable fibrillar Type I Collagen has failed,...until now.
- Process results in elasticity not previously seen and suitable for matrix/scaffold formation and most useful in a multitude of medical devices.
- Fibrillar Dimension – maintenance/preservation of fibrillar dimension and associate thermal stability is critical. This has apparently been missed by previous processing techniques.
- Predictability - the material that is the subject of our invention has been carefully guided in isolation and purification to result in a form unique to fish tendon sourced collagen. Although it has been sought by others, the process to secure it was not predictable. Once the process was secured, it was 'explainable' but, in retrospect, this is not anticipation or prediction. In fact, the conspicuous historical absence of the material while being pursued by others, points to its uniqueness and our processing discovery. Had the result of our invention been anticipated by any previous work, it would have appeared. Our process provided an opportunity to observe an irregular and unexpected event in the form of a very unusual fibrillar form which could be further processed into a most suitable platform of medical devices comparable to those of mammalian origin and uncompromised by mammalian diseases or contaminants.
- Our invention has provided a process for the discovery of a unique fish tendon fibrillar fiber which had avoided discovery for more than sixty years of collagen research & development.

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